United Fresh Fruit &
Vegetable Association

July 23, 2004

Division of Dockets Management
HFA-305
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0258, Produce Safety From Production to Consumption, 69 Fed. Reg. 33,393 (June 15, 2004)

Dear Sir or Madam:

Founded in 1904, the United Fresh Fruit and Vegetable Association (United) is the leading, national trade group representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry; promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

United Fresh Fruit & Vegetable Association is 100% committed to food safety. Over the last decade, the produce industry has invested considerable time and resources to improve food safety from farm-to-fork and our efforts have clearly made a difference. The produce industry has gone through tremendous changes in an effort to remain profitable, satisfy consumer demands, conform to new technologies, and to compete in a global marketplace—all the while focusing on the safety of our products. The industry continually examines the latest scientific information to improve food safety practices. More companies than ever are using Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), worker health/hygiene programs, and Hazard Analysis and Critical Control Points (HACCP) programs. However, we also know that this is just a beginning and there is more work ahead.

With this in mind, we have a direct and vested interest in the development of the Agency's proposed action plan to minimize foodborne illness associated with the consumption of fresh produce, and we fully support the constructive and effective components of the Food and Drug Administration's (FDA) initiative, "Produce Safety from Farm to Consumption." United was pleased to provide comments at the public meeting held on June 29, 2004, outlining our initial thoughts on the key components of any produce safety initiatives undertaken by the Agency. We would like to expand upon those thoughts and provide the following for consideration as the action plan is further developed and implemented.

The *Federal Register* notice announcing the June 29th meeting included a targeted list of nine questions participants were asked to consider in their public comments. At that time, the actual "plan" had not been publicly released. The Agency has now published its proposed strategy, "Produce Safety from Production to Consumption: A Proposed Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption," and is requesting input on its content. Our comments will be directed specifically at the draft plan.

United must again note, as we did in our comments filed last week that these substantive comments cannot possibly constitute the end of this discussion. The issues presented by the Proposed Action Plan are too important to address in a single thirty-nine-day comment period. We look forward to continuing discussions with the agency to more fully develop our responses to FDA's inquiries.

General Comments:
The Produce Safety Action Plan establishes a set of four possible objectives to meet the stated goal of minimizing foodborne illness associated with the consumption of fresh produce. Additionally, the Agency wishes to measure the success of implementation of the Plan and whether the plan "has had a concrete, positive effect on the public health risks."

We believe the Action Plan should include an effective means of measuring the success of actions taken. To do this, the Center for Disease Control and Prevention (CDC) must first establish baseline data against which progress can be measured. Relevant baseline data might include data on compliance with GAPs and GMPs, but most importantly it should include data on incidence of foodborne illness outbreaks and cases associated with produce. Ideally, this information should be commodity-specific and should relate all case numbers to true commodity consumption numbers. Using actual consumption/case data, the FDA could then compare over time the difference between incidence rates from year to year. For example, if we know the number of eating occasions per year for a specific food item, the number of overall foodborne illnesses per year and the actual number of illnesses associated with the given food item per year, then we could determine the percentage of produce related illnesses for that commodity. This information would be invaluable in that we could tailor our food safety systems to those areas that present real risk to the consuming public. Definitively addressing potential sources of contamination and risk will be a benefit to all producers, buyers, and consumers, and will ultimately improve consumer confidence.

United also believes that the Action Plan, while already broad, should be comprehensive. In order to maintain that consumer confidence of produce in general, we believe that the plan should cover all fresh and minimally processed (*i.e.*, processed without a kill step) fruit and vegetable products, including frozen fruits and vegetables, as well as other commodities typically eaten raw such as tree nuts. Any outbreak associated with produce, whether fresh or further processed, has an impact on public health and consumer confidence in the safety of fruits and vegetables generally. In addition, any approach taken by the FDA must incorporate the entire supply chain from the farm to the consumer. Insofar as existing data shows that most food borne illness outbreaks traced to produce involve downstream contamination, the Action Plan must encompass retailers, foodservice, and consumers.

United's Response to the Plan's Outlined Objectives:

Objective #1:
The first objective of the plan is to "Prevent Contamination of Fresh Produce with Pathogens." We concur that prevention of contamination is the critical step in addressing produce food-safety. The Agency outlines key steps to prevention such as promotion of the current GAPs and GMPs and the development of additional commodity specific guidance and retail guidance. It truly makes sense to focus on these action items.

In the mid 1990s, our industry and the FDA undertook a systematic and thorough look at best agricultural practices for growing and packing fresh produce. As part of the 1997 Produce and Imported Food Safety Initiative, FDA and the U.S. Department of Agriculture (USDA), in cooperation with the produce industry, developed voluntary guidance on good agricultural and good manufacturing practices (GAPs/GMPs) for the growing and packing of fresh fruits and vegetables. Based on the very best science available, FDA's 1998 publication of *Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* has been instrumental in driving ever increasing attention and commitment to reducing risks throughout our industry. United has strongly encouraged its members to adopt the practices covered in the *Guide*. Representatives from the produce industry have also assisted in the development and implementation of educational programs based on the *Guide* for growers and packers of fresh produce.

Since that time, our association has developed *Food Safety Auditing Guidelines* to help our industry measure compliance with these standards; worked with numerous universities, state departments of agriculture and USDA to provide field education, and enlisted buyers of fresh produce at retail and foodservice to specifically ask suppliers about their safety practices.

The current GAPs and GMPs are excellent and represent the best available science-based food safety recommendations for the produce industry. At this time, we do not see any need for revision. The existing GAPs/GMPs already identify the major practices that may contribute to contamination of fresh produce at the grower and packer level. However, we know that there is not 100% recognition and implementation of the GAPs/GMPs throughout the entire industry. We believe that it is essential to continue promotion of the GAPs/GMPs guidance to primary production operations within the produce industry. As noted above, United has invested considerable time and resources into this effort. However, more work and resources are needed <u>from the Agency</u> to ensure all producers are aware of, understand, and apply the GAPs/GMPs appropriately in their operations. FDA must implement this action step immediately and commit all of its available resources to the GAPs/GMPs promotion effort. United will support any and all efforts to that end.

Produce safety must be considered throughout the supply chain, but the promotion of the current GAPs/GMPs directed at producers should come first. Only after the industry has achieved full recognition and implementation of the current guidance should any commodity-specific or retail/foodservice guidance be developed by the Agency.

Once the current GAPs are universally implemented, we do believe that the development of commodity-specific and sector-specific guidance, such as guidance for fresh-cut produce operations and retail/foodservice, is appropriate and warranted. All segments of the food

industry must take responsibility for the safety of products they produce. Yet, many may not have the knowledge, skills or ability to incorporate produce specific safety measures into their overall food safety systems. We must be vigilant in providing the necessary assistance to these food industry segments keeping in mind that any guidance geared towards specific commodities or food sectors must be developed with strong input and science-based recommendations from the produce industry to ensure future adoption and success. The guidance should be risk-based and recognize and respond to new risks as they arise. Additionally, all guidance should be easy to understand and implement in real-world food processing environments for widespread adoption of the practices.

Objective #2:
The second objective is to "Minimize the Public Health Impact When Contamination of Fresh Produce Occurs." The Agency's proposed action steps to achieve the objective have the potential to increase surveillance, sampling and inspections.

First, we would like to comment, in general terms, on the proposed action items outlined in Objective #2. These actions in and of themselves will not necessarily meet the stated objective. Sampling, surveillance, and inspection alone will not reduce outbreak numbers or foodborne illnesses cases. Microbiological risk cannot be inspected or sampled away. Microbial contamination of produce typically is sporadic and unevenly distributed. As a result, sampling produce for pathogens is similar to looking for a needle in a haystack. We need more scientific evidence of how contamination is most likely to occur, and less speculation on theories that take industry and government attention away from more likely risks.

Instead of viewing sampling and inspection as food safety interventions, we believe that the Agency should focus its surveillance, sampling and inspection efforts in a manner that will help to answer the all too often "unanswered" questions of "How could a certain pathogen have found its way into the food supply? Where is the contamination most likely to have occurred? What steps or procedures could have been taken to prevent the contamination in the first place, or reduce its impact along the food chain?"

The industry would support more detailed foodborne illness outbreak investigations and reporting from CDC to assist in answering these questions. At present, outbreak data provides only the number of cases, the pathogen, and the product that served as the vehicle of transmission. From this limited information, it is very difficult to determine the source of contamination or to obtain practical information that would assist stakeholders along the supply chain in preventing a recurrence. If outbreak data provided more detailed information including the likely source of contamination, specific practices at each level of the supply chain that may have contributed to the problem, and measures that might have been taken to prevent, reduce, or eliminate the contamination, then food handlers and consumers would be better able to use this "lessons learned" information in developing strategies to prevent future occurrences and thus actually have an impact on public health.

When these unfortunate outbreaks occur, we must not be satisfied with generalizations or hypothetical opinions; we must use every scientific method possible to determine the specific cause of the problem, and ways in which product handling and preparation may have exacerbated the problem. Because fresh produce is highly perishable, by the time produce has been implicated in an outbreak, usually the implicated food item is long gone from distribution,

and cannot be directly examined. But we still need FDA, CDC and industry to leave no stone unturned in learning the lessons science allows.

We do support increased sampling and inspection if it will assist FDA in providing the industry with valuable information regarding industry adoption of safe handling practices throughout the supply chain and the development of new cost effective and efficient food safety preventive measures. But, United views sampling primarily as a way to gather baseline data on microbial contamination of produce and to measure progress. Therefore, we propose that sampling be conducted broadly and not limited to produce items with a history of outbreaks. Also, the sample collection, analytical methods and procedures used should be well thought out and discussed with the produce industry so that the data generated will ultimately be used to develop new strategies to further reduce the incidence of foodborne disease.

Further, it is important that those individuals charged with inspection of the produce industry be familiar with food safety in all produce environments. In essence, they must have the knowledge, skills and ability to perform their job functions. FDA must focus its efforts and resources on the training of FDA personnel involved in produce-related investigations and routine inspections. Having trained investigators would be a benefit to the industry and would ensure better performance during routine inspections and outbreak investigations.

Objective # 3:
The third objective is to "Improve Communication with Producers, Preparers and Consumers about Fresh Produce." This section focuses on communication strategies and education. FDA proposes to establish a protocol to ensure that consumers are informed as quickly as possible of outbreaks and to establish a mechanism to ensure prompt communication between federal, state, and local food safety agencies, foreign governments, and the private sector when there is cause for a food safety concern.

We agree with the FDA's desire to establish protocols to ensure effective consumer and regulatory communication during crises. However, any such protocols must have industry input. For example, the protocol developed to alert consumers of potential problems must be agreed upon prior to implementation to ensure effectiveness.
We believe that FDA needs to better communicate the critical importance of safe production and handling practices at every level in the supply chain, including consumers, to reduce risk for all. Food safety is everyone's responsibility; it starts at the farm but it does not end until the consumer enjoys a healthy, nutritious and safe produce item. Any rational plan must include an educational component whereby the general public can be brought to understand that home handling practices can help protect their families from inadvertent contamination.

However, any awareness programs implemented must be tailored to ensure that the programs themselves do not unwittingly frighten consumers away from eating produce. The consumer cannot be left with the impression that produce carries significantly different or worse food-safety risks than other foods. Eating more fruits and vegetables is the number one dietary recommendation for Americans, and a constant in each edition of the *Dietary Guidelines for Americans*, and actions taken in the food safety arena must not compromise this critical public health message.

Regarding communication with industry, United would be supportive of continued education efforts at a grassroots level both domestically and internationally. Educational efforts by FDA, USDA, state and local governments and universities should address specific produce safety needs at each stage of the supply chain from farm to table, specific produce safety needs by commodity, and if necessary, specific produce safety needs for certain produce growing and packing regions. FDA should more fully engage and collaborate with trade organizations, educational institutions and other potential partners in developing a portfolio of food safety training materials.

As for content, FDA should consider the entire realm of knowledge potentially needed to enhance all areas of food safety related to produce operations. For example, courses might be developed covering such topics as Worker Health & Hygiene in the Produce Industry; Produce GAPs, GMPs and HACCP Programs; Produce Agronomic & Post Harvest Practices; Agricultural Water Quality in the Produce Industry; Produce Food Law; Traceback, Recalls and Transportation in the Produce Industry; and Produce Food Safety Documentation and Management Programs. A number of these programs could be conducive to formal certification of food safety personnel involved in produce handling along the supply chain. In addition, educational plans should focus on the development of tools and materials that can be provided electronically through websites, cd-roms, videos, and similar media. It is increasingly difficult for company personnel to travel for education, so making educational materials portable and user friendly is always beneficial.

Once education programs are developed and implemented, the Agency should assess their impact on food handler and consumer behavior. We would be happy to provide input and assistance in developing evaluation criteria for these educational efforts.

Objective # 4:
The fourth objective is to "Facilitate and Support Research Relevant to Fresh Produce." Research is an area that must be addressed in the plan and we applaud FDA for its inclusion. We concur that there needs to be a better understanding of why these rare produce-related outbreaks occur. What went wrong in the process from the field to the table? Only with that detailed knowledge can we apply the tools at hand to prevent future outbreaks.

With limited resources, it is our belief that research funds should be directed towards practical research initiatives that would ultimately be the most beneficial to industry stakeholders along the supply chain. USDA Agricultural Research Service (ARS), FDA, and USDA CSREES-funded organizations have conducted research on "identified" risks for producers, processors, and consumers since the 1990's. However, we do not know if the information resulting from these produce-specific research studies have had an impact on food handler and consumer behavior, have reduced risks along the supply chain, or have resulted in new and effective preventive measures. For allocating funds to future research initiatives, we must ensure that the designs of studies allow for measurable results.

United believes that basic research is always valuable regarding microbial ecology, molecular mechanisms involved in product contamination, the array of pathogens confronted, the epidemiology of foodborne illness, and control measures from farm to table. However, research data that results from the controlled environment of a laboratory setting is far less useful than data from research performed in real produce operations. To that end, research conducted under

the Action Plan must be performed in real produce supply chain settings. Supply chain research could include baseline sampling throughout the chain; baseline, regional water quality information; microbial ecology for specific produce items and agricultural inputs; and specific pathogen-produce pairings. Research results should be shared with stakeholders promptly and should be presented in a manner that does not create undue fear about obscure, hypothetical risks.

At the end of the day, research should generate practical information that enables stakeholders to incorporate efficient and cost effective measures into their operations as appropriate.

Final Thoughts:

We thank you for this opportunity to comment on the Produce Safety Action Plan. While the perishable nature of our products present unique challenges in highly volatile markets, the industry has always taken its food safety responsibility very seriously and is committed to providing a safe, abundant, and affordable fresh produce supply. The produce industry is proud to produce a product that is the centerpiece of a healthy diet, and we do not want the risk of foodborne illness to detract in any way from the positive public perception of produce or the potential health benefits consumers may enjoy from increased produce consumption. Produce industry members are eager to resolve issues associated with food safety where evidence indicates that problems exist and appropriate solutions can be developed. We look forward to continuing to work together with FDA on these important matters and continuing to submit additional comments as the Agency moves forward with priorities set forth in the Produce Safety Action Plan.

Respectfully submitted,

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President and CEO
United Fresh Fruit and Vegetable Association

Please Note: These detailed comments provided are supported by the Georgia Fruit and Vegetable Growers Association, Grower-Shipper Association of Central California, International Banana Association, and Texas Produce Association.